

REMARKS

There are 18 claims pending in the application, comprising claims 28-45, for the Examiner's review and consideration. A Rule 132 declaration of Mr. Barry Kauker, a person of ordinary skill in the art, is enclosed. Mr. Kauker is a Principal Engineer with Stryker Endoscopy (Assignee) and with over 22 years experience in the Medical Device Product. He is named inventor on 9 patents covering a variety of products used daily in the operating room and has other patents pending. Mr. Kauker is submitting this declaration as one of ordinary skill in the art in support of the patentability of the invention.

In the present Office Action, claims 28-29, and 32 have been rejected over the combination of US patent 3,807,526 to Sygnator and US patent 5,327,178 to McManigal, claims 30-31, 33-35, 37, and 39 have been rejected over the combination of Sygnator, McManigal, and US patent 6,176,576 to Green, claims 38, and 40-45 have been rejected over the combination of Sygnator, McManigal, and US patent 6,091,546 to Spitzer, and claim 36 has been rejected over the combination of Sygnator, McManigal, Green, and US patent 3,781,492 to Cragg. Applicants repeat and adopt herein all comments made in prior responses and traverse these rejections.

Before addressing the rejection, brief review of the features of the present invention may be helpful. The present invention is primarily directed to a surgical operating theater where much of the wearer's lower face is typically covered by a surgical mask and much of the head is covered by a surgical cap. The eyewear comprises a microphone, a speaker, and an eyewear neck strap that couples the microphone and speaker to a wearer unit carried by the eyewear wearer. The wearer unit exchanges wireless signals with a base station. The base station is coupled to various devices such as surgical theater equipment, and/or to a telecommunication system, such as a telephone system.

Although a large housing or a boom can be used to position a microphone close to the wearer's mouth, medical personnel, especially surgeons, prefer to keep as much equipment as possible away from their face and away from the mask and cap. If a boom is used, the microphone position can be altered if the boom is displaced when removed from the wearer's head. A boom can snag on other objects. Thus an advantage of the integral microphone housing is that the wearer is unaware of the microphone's presence. The microphone remains in the correct position during eyeglasses use and storage, and no microphone position readjustment is required.

Mr. Kauker confirms in paragraphs 2-3 of his declaration that “the claims of this invention are directed to improvements in protective eyewear that includes a communication system built into the eyewear and the provision of the ability to clearly hear environmental audio inputs.” “The eyewear enables the wearer to conduct hands-free communication such as telephone conversations and command and control operations. The eyewear is also configured such that speaker is held away from the wearer's ear so that a gap exists between speaker and the wearer's external outer ear. This gap is made large enough so that external sound is not obstructed from reaching the wearer's ear canal.” He also confirms that “[i]n an operating room it is absolutely critical that the surgeon be completely aware of what is going on around him or her at all times. Configuring a speaker system with an air gap allows the surgeon to clearly hear what is going on within the operating room while at the same time getting the information he needs through the speaker system attached to his protective eyewear.” “The present invention solves the concerns of audible obstruction and speaker placement and makes the operating room a safer place to perform surgery.”

The Office Action argues that “Sygnator intended to reduce to tolerance levels the high decibel sounds (col. 1, lines 27-30). In other words, Sygnator only concern to high decibel sounds.” Applicants completely agree with this assertion of the Examiner, however, as attested in paragraph 6 of Mr. Kauker's declaration, “It is important to note that this is necessary in Sygnator because the sound intensity of industrial equipment, such as a punch press, can be as high as 112 dB, while acceptable sound intensity for an eight hour period is 85 dB. An effective protection device such as that taught by Sygnator needs to reduce the sound level from 112 dB to about 85 dB, a reduction of 27 dB or approximately a 22 times reduction in loudness. Further, the intensity level of a normal conversation is 60 dB, a significantly different level from the punch press intensity (approximately 1/400 times the loudness level of a punch press). A passive device, such as Sygnator, designed to address the high decibel noise levels occurring in the industrial operations, cannot effectively function as a protective device and at the same time permit the wearer to hear environmental sounds without significant obstruction, as any reduction applied to high decibel levels would also be applicable to environmental sounds. It is clear that a 22 times reduction in loudness of normal conversation level, cited in the above example, is a significant reduction.” Thus, while Sygnator device intends to reduce to tolerance levels the high

decibel sounds, it can not avoid reducing other environmental sounds to effectively the same degree as the high decibel sounds.

The Office Action further argues that “Sygnator further teaches bendable arm to adjust pressure on the ear, i.e., moving inward or outward.” While Sygnator does teach an inward bendable arm, there is absolutely no teaching or suggestion on outward bending arm. In this respect, the following excerpts from Sygnator's specification help to provide insight to whether there is any teaching or suggestion on outward bending arm:

This arm 14 is offset, as at 16, outwardly from the adjacent temple bar and is angled downwardly and rearwardly to overlie the tragus, antitragus and concha area of the ear and may be enlarged toward the free end 15 thereof which serves as a sound interference barrier against the full effect of external high decibel sound reaching the inner ear through the auditory canal. (col. 2, lines 1-8, emphasis added)

This use of the device would probably be limited to actuations where the duration of wearing the glasses is not such as to cause discomfort to the wearer by this constant inward bending pressure on the tragus. For this purpose and for the purpose of adjusting the arm 14 and end 15 thereof to the ear configuration of a particular wearer, the arm 14 may be made of resilient and bendable plastic material, or even core reinforced plastic material, as in many temple bars for limited adjustable fitting purposes, or of light weight metal consistent with the desired lightness and comfort to the wearer. (col. 2, lines 26-37, emphasis added)

Thus, the two purposes of bendable arm are for application of inward pressure and for adjusting the arm and end to ear configuration, neither one of which requires outward bending. It should be noted that for appropriate ear configuration, as cited above, the arm is angled downwardly and rearwardly to overlie the tragus, antitragus and concha area of the ear, and not bend away outwardly from the ear. This selective, unsubstantiated and contradictory interpretation of Sygnator's discloser is an attempt at hindsight reconstruction of the present invention.

The Office Action also argues that “Sygnator discloses [this structure] in column 2, lines 17-22.” and that “[e]ven with this rather loose overlying disposition of the end portion 15, it has been found that a substantial amount of high decibel sound is prevented from reaching the inner ear, thus reducing the possibility of injury thereto.” However, as attested in paragraph 7 of Mr. Kauker's declaration, the Office Action is “citing an entirely separate embodiment from the embodiment that is used for the analogy to the independent claims of the present invention. It is important to note that these two embodiments are mutually exclusive. The embodiment

used for the analogy includes a pad "that is intended to overlie a larger area of the concha", while the other embodiment does not include a pad, and as such, the performance of these two embodiments significantly differs. The embodiment with a pad "will have a correspondingly greater barrier effect as perhaps comparable to placing the palm of one's hand over the ear rather loosely" (*see* col. 2, lines 56-59). As mentioned above, in an OR it is absolutely critical that the surgeon is completely aware of what is going on around him or her at all times, and thus, having the surgeon's ear covered as if by placing the palm of one's hand over the ear, even rather loosely, is entirely unacceptable, as such configuration would most certainly compromise communications and possibly endanger the life of the patient. Thus, in the view of a person of ordinary skill in the art, Sygnator does not disclose, teach or suggest the presently claimed invention."

With respect to applicants' prior assertion that McManigal teaches away from Sygnator rather than suggesting a modification of Sygnator, the Office Action argues that "Syngator does not expressly discloses to eliminate other environmental sounds". As attested in the declaration by Mr. Kauker, "McManigal intends to provide the individual quality sound from a personal audio source, without speakers touching the ears, and/or without interfering and blocking surrounding sounds from the environment. Sygnator's teaching of preventing or blocking the hearing of ambient sounds is completely contradictory to McManigal's teaching. As discussed above the Sygnator's device would equally reduce both the high decibel sounds and other environmental sound, thus, a skilled artisan, well aware of this fact, would not attempt to combine these teachings since any advantage provided by one teaching would be at the cost of the other teaching. This inconsistent approach is illogical and does not support the rejection."

The declaration establishes that there is no relation between the Sygnator and McManigal patents that would suggest what is claimed in the present application, and that a skilled artisan would not be motivated to develop the present invention in view of the lack of relevant teaching between those documents.

As further attested by Mr. Kauker in paragraph 10, the same is true of the rejections that add the Spitzer, Green or Cragg references to the combination of Sygnator and McManigal, as Spitzer, Green and Cragg "references do not provide any disclosure that would remedy the deficiency of the Sygnator and McManigal references to render the present claims obvious." Thus, this declaration is also evidence that overcomes the Examiner's suggestions that

the invention is obvious, since as a skilled artisan the invention provides unexpected benefits and was not obvious to him.

For the foregoing reasons, applicants submit that all of the claims are patentable over the cited art and respectfully requests reconsideration and an early indication of allowance. The Examiner is invited to contact the undersigned if any additional information is required.

Respectfully submitted,

24 July 2007
Date

for



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